REMARKS

Independent claims 1, 13, 14, and 15 are amended to overcome the rejections in view of the cited reference.

Dependent claims 2-3 and 6-12 are amended to improve punctuation.

Dependent claim 16 is amended to claim a feature similar to that in claim 2 because original claim 16 included the same features as claimed in the determining step of independent claim 15 on which claim 16 depends. Therefore, original claim 16 was redundant.

Support for the amendments is found, for example, in the existing claims and in the present specification, as cited herein below.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by McIlroy, et al. (US Patent No. 5,5583,758 A) (hereinafter "McIlroy").

McIlroy teaches, in relevant part, as follows:

In the Abstract:

> [57] **ABSTRACT**
>
> A health care management system for use by hospitals, physicians, insurance companies, health maintenance organizations, and others in the health care field includes a processing unit and health condition guidelines. A user inputs information related to the health condition of an individual and guideline treatment options are identified. The user also inputs actual or proposed and final recommendation treatments for the same individual. The resulting comparative information can be used to modify the actual or proposed treatment, or provide explanatory information as to reasons for the difference between the final recommendation treatment and guideline treatment options. Also, the comparative information can be used by a reviewer for evaluation or utilization purposes.

At col. 7, lines 45-53 (Guidelines):

> Diagnosis-based guidelines provide a framework to reflect the critical factors in the clinical decision process usually leading to treatment, to define optimal resource allocation, and to outline key patient data. A guideline is not a fixed formula or cookbook, although it must be a definite, step by step algorithm that can be coded; rather, a guideline presents a disciplined framework or process to guide and assist the user, such as a health care provider, in identifying appropriate treatment.

At col. 10, lines 13-23 (Process for updating guidelines):

> Guidelines are continuously updated by recurring searches by diagnosis for new findings and studies. Also each guideline can be reviewed on a periodic basis, such as annually. Information from the care management system can be retrieved for that review, including results of use, frequency of use, frequency of variation by component, type of variations. Because the present invention implements the guidelines as data base parameters, the system is flexible; it can be readily adapted to changes in and evolution of health care professional knowledge and treatment methods.

At col. 18, lines 16-25 (Reports):

> Information management reports identify overall volume and patterns of care including diagnosis, therapeutic selection and resource use. From these reports, you can determine the level of effectiveness or impact related to each guideline use. You can also use the reports for quality measurement and planning by identifying where variations are occurring and how they are resolved at the initial guideline level. Reports may be selected by date in either clinician identification number or reviewer identification number or both. They are sorted automatically by specialty area.

The present specification teaches, in relevant part, the following:

At page 9, line 18 to page 10, line 8:

"In the preferred embodiment of the present invention, the system 100 and the method 200 provide an aggregate analysis of orders and documentation generated by healthcare clinicians, such as physicians. Using correlation techniques, such as clustering, sets of frequently associated orders and documentation elements are identified. Through analysis of the correlation contents, and associated patient information, the rationale for each correlation is identified. Ongoing surveillance permits the observation of changes to

correlation contents, such as the appearance of new diagnostic/therapeutic measures for a given condition. This is used in concert with an alerting mechanism to inform an editorial board of the changes in observed clinical practice, providing an explicit mechanism for identifying order sets and/or documentation templates that require modification.

The system 100 and the method 200 provide a much lower effort to value ratio, by observing changes in medical practice which have been adopted by healthcare clinicians, and using these changes to alert an editorial board of the need for review. The system 100 and the method 200 assume that the healthcare clinicians in practice are monitoring the literature in their field and the evolving knowledge within their specialties, and are making appropriate decisions regarding when to incorporate new behaviors into their practice. Thus, the system 100 and the method 200 avoids the deficiencies of a centralized approach, wherein the editorial board that makes decisions about new clinical information is isolated from issues, such as cost, reimbursement, patient acceptance, and patient impact, regarding the adoption of the new information. By the system 100 and the method 200 reviewing (i.e., conducting surveillance) a large sample of clinical practice information, the emergence of new items associated with previously identified clusters, and the rate of change of their adoption, appropriate targets for inspection may be identified."

At page 13, line 21 to page 14, line 2:

"At step 206, the method 200 initiates generation of a message 212 to alert a message recipient (e.g., a user of the client 102) of an identified potential change in use of the particular treatment. Preferably, the potential change in use of the particular treatment includes, without limitation, a change in frequency of use of the particular treatment by physicians to treat the particular medical condition and/or a change in type of medical condition treated with the particular treatment. Preferably, at step 206, the method 200 initiates generation of a message prompting a user with a suggestion of an additional order item to be added to an existing order set documentation template, and/or a deletion of an order item from an existing order set documentation template. Hence, at step 206, the method 200 provides a notification mechanism for newly identified correlated data (i.e., clusters), and of emerging changes of cluster membership, through the functionality of a selection list provided by the selection-list generation engine 124 (FIG. 1). Preferably, the message processor 118 performs step 206 of the method 200."

At page 13, line 21 to page 14, line 2:

"In the preferred embodiment, an order set and documentation template is a self-learning system 100 and method 200, which observes orders and documentation elements related to specific clinical indications, and aggregates their frequencies and configurations, so that these can be rolled into new and updated order sets. The advantages of the system 100 and the method 200 include, without limitation, the following:

1. They provide a mechanism for developing and maintaining order sets that remain current with real clinical practice

2. They avoid the implementation hurdles associated with transferring standards between institutions.

3. They provide for automated generation of order sets for every new specialty and procedure.

4. They improve implementation order sets, by filling in missing items, and by filling in missing order sets.

5 They reward physicians for bothering to include new orders by incorporating their changes into evolving order sets."

At page 24, lines 10-17:

"Hence, the system 100 and the method 200 observe changes in ordering patterns of actual clinical practices to aggregate data. The system 100 and the method 200 analyze the data to create a set theory model 126 representing those patterns. The system 100 and the method 200 evaluate the model to target the membership of order sets using specific rationales. The system 100 and the method 200 permit manual review for manual validation. The system 100 and the method 200 evaluate changing memberships within the model 126 and provide self-monitoring, automated, notification of those changes to permit update in the order sets and/or other clinical documentation."

Analysis of the claimed invention in view of the teachings of McIlroy.

The claimed invention is an improvement and distinguished over the teachings of McIlroy for the following reasons.

As claimed in the independent claims, the orders are "generated by healthcare clinicians," and a "number of orders" are analyzed for a "determination" related to "changed significance," "a predetermined threshold," and/or "a rate of change." In response to such "determination," an "alert message" or "suggestion" is "automatically and proactively"

"initiated" or "prompted" to "permit review and potential modification at least one order for said particular treatment." In other words, as claimed, and as supported by the present specification, as cited herein above, the present invention provides an automatic and proactive *feedback mechanism* (as reflected in the claim language) to permit efficient consideration for modification of the orders in the system. McIlroy does not teach or suggest the same.

McIlroy teaches an old, prior art method of "updating the guidelines," as taught at col. 10, lines 13-23 (Process for updating guidelines), cited herein above.

McIlroy's old, prior art method, and its associated problems, is also described in the background of the present specification at page 2, line 21 to page 3, line 5, as follows:

"Unfortunately, growth of the quantity of each of the order sets and the documentation templates create a burden on personnel and/or systems to maintain (i.e., review and update) the order sets and the documentation templates. Further, it is difficult to provide consistency for individual elements, which appear in multiple order sets and multiple documentation templates, because each order set or document template is developed and maintained individually.

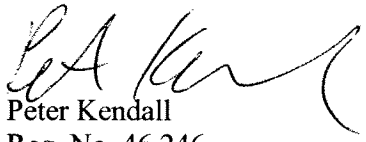
Various approaches to maintaining order sets and the documentation templates are inadequate. Common approaches include the systematic review of medical literature, identification of important changes in practice, review by expert committees, and when deemed appropriate, the inclusion of any changes in the appropriate members of each of the order sets and documentation templates. Alternately, the contents of the order sets and the documentation templates are systematically reviewed in a rolling fashion, providing for a periodic refresh of each template. Both approaches require a very high effort to value ratio, either reviewing an enormous amount of literature in order to identify a relatively small number of required changes, or reviewing an enormous number of order sets and documentation templates on a periodic basis to identify a relatively small number of needed changes."

McIlroy does not teach or suggest how to overcome these problems, as presently claimed, and as supported by the present specification to provide the advantages of the present invention, as described in the present specification and cited herein above.

Therefore, for at least these reasons, claims 1-16 now appear to be patentable over McIlroy.

In view of the above amendments and remarks, Applicants submit that the Application is in condition for allowance, and favorable reconsideration is requested.

Respectfully submitted,



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